Translation

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PATENT COOPERATION TREATY

PCT/EP2003/014713

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 02/085 NUT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP2003/014713	International filing date (*day/month/year*) 22 December 2003 (22.12.2003)	Priority date (*day/month/year*) 24 December 2002 (24.12.2002)
International Patent Classification (IPC) or national classification and IPC A61K 35/78		
Applicant NUTRINOVA NUTRITION SPECIALTIES & FOOD INGEDIENTS GMBH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand 14 July 2004 (14.07.2004)	Date of completion of this report 15 April 2005 (15.04.2005)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

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International application No.
PCT/EP2003/014713

I. Basis of the report

1. With regard to the elements of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-17, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☒ the claims:

pages _____, as originally filed
pages _____, as amended (together with any statement under Article 19
pages _____, filed with the demand
pages 1-19, filed with the letter of 13 December 2004 (13.12.2004)

☐ the drawings:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed
pages _____, filed with the demand
pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

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III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1, 11, 14 (partly)

because:

☐ the said international application, or the said claims Nos. _____ relate to the following subject matter which does not require an international preliminary examination *(specify):*

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____ are so unclear that no meaningful opinion could be formed *(specify)*:

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 1, 11, 14 (partly) .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: BOX III

As already extensively dis ussed in the international search report, the current claims 1, 11 and 14 relate, *inter alia*, to an active substance characterised in terms of a desirable property, namely its cholesterol-lowering effect. The claims therefore encompass all the products, etc. which show this effect or property, yet the application provides support in the description (PCT Article 5) for only a limited number of such products. In the present case the claims lack the proper support and the application lacks the requisite disclosure to such an extent that it does not appear possible to carry out a meaningful search covering the entire range of protection sought. Regardless of the above, the claims also lack the requisite clarity (PCT Article 6) since they attempt to define the active substance in terms of the desirable property which is to be achieved. Again, this lack of clarity is such that it is not possible to carry out a meaningful search covering the entire range of protection sought. The search was therefore directed to the parts of the claims that appear to be clear, supported and disclosed in the above sense, namely the parts that relate to the active substances listed on page 9, paragraph 3 of the description, i.e. statins, bile acid resorption inhibitors, bile acid sequestrants, cholesterol absorption inhibitors, fibrates, nicotinic acid derivatives, phytosterols, plant stanols and cholesterol-lowering plant extracts.

The applicant is again advised that claims or parts of claims relating to inventions in respect of which no international search report has been established cannot

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: BOX III

normally be the subject of an international preliminary examination (PCT Rule 66.1(e)). In its capacity as International Preliminary Examining Authority the EPO generally will not carry out a preliminary examination for subjects that have not been searched. This also applies to cases where the claims were amended after receipt of the international search report (PCT Article 19) or where the applicant submits new claims in the course of the procedure under PCT Chapter II.

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International application No.
PCT/EP 03/14713

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-19	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-19	NO
Industrial applicability (IA)	Claims	1-19	YES
	Claims		NO

2. Citations and explanations

The subject matter of claims 1-19 is not considered inventive for the following reasons.

EP-0616780 **(D1)** describes natural carob fibres with cholesterol-lowering properties and processes for producing the same.

EP-1203535 **(D2)** shows the use of cereal germ flour, for example carob, wheat, rye, maize or their mixtures, for producing phytate-rich foodstuffs for treating or preventing pathological or prepathological phytate-deficiency states. A favourable effect of phytates is their ability to lower the concentration of cholesterol and triglycerides in blood, with positive effects on cardiovascular diseases.

WO-A-0343659 **(D3)** describes oral administration compositions which contain a mixture of a statin, DHA, vitamin E, etc..., together with a suitable carrier, and which are particularly useful as dietary supplements administered in order to reduce cardiovascular disease risk factors, such as increased serum cholesterol level and high blood pressure.

WPI 1987-118804 **(D4)** reports on a lipid metabolism accelerator for weight control and reduction of blood serum cholesterol, the accelerator containing garlic extract as active substance.

D5 (Marie-Pierre St-Onge *et alia*) shows that a mixture of triglycerides having a medium chain length, phytosterols and linseed oil has a protective effect against cardiovascular disease, by reducing blood lipid parameters, and can certainly be used for weight regulation.

D6 (H. Drexel, F. Follath, 1993) reports that fibric acid derivatives, nicotinic acid and omega-3 fatty acids effectively lower VLDL.

D7 (John A. Farmer, A. M. Gotto, 1996) is an overview of various lipid-regulating agents (such as nicotinic acid, HMG-CoA-reductase inhibitors, fibric acid derivatives, etc...), their mechanisms and effects on lipids.

In conclusion, it can be determined that the individual components of the claimed cholesterol-lowering agent and their individual cholesterol-lowering properties were already known in the prior art. As long as the synergistic effect asserted by the applicant (see page 13, last paragraph; page 14, first complete paragraph; and page 15, paragraphs 2 and 3), as well as the presumed shift of the HDL/LDL ratio to the "good" HDL cholesterol (page 5, paragraph 4), are not validated by experimental data, an inventive step cannot be recognised.